

REMARKS

Claims 69, 70, 72, and 74 are pending and under consideration in the application.

At the outset of the Advisory Action, the Examiner states, “[a]pplicant’s amendment filed on July 12, 2005 is acknowledged but will not be entered because it does not place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Specifically, the claims as amended do not satisfy the issues raised under 35 U.S.C. 112 first paragraph as lacking enablement.” See Action at page 2, item 1. Applicants, however, did not amend the claims in the July 2005 Response. Thus, applicants assume that the above statements by the Examiner were made in error, and that the claims under consideration by the Examiner are the claims as amended in the Amendment filed on October 18, 2004. Also, applicants request that the July 2005 Response be entered.

35 U.S.C. § 112, first paragraph

In the Final Office Action mailed January 12, 2005, the Examiner rejected claims 69, 70, 72, and 74 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. See the Final Action, at page 3, item 5. Specifically, the Examiner alleged that “...the specification, while being enabling for a method of enhancing a nucleic acid polymerase comprising (a) forming a nucleic acid polymerase reaction composition comprising (i) a nucleic acid (ii) at least one nucleic acid polymerase, wherein said polymerase is Pfu DNA polymerase and..., it does not reasonably provide enablement

for a method of enhancing a nucleic acid polymerase reaction comprising: forming a nucleic acid polymerase reaction comprising: (i) a nucleic acid and any nucleic acid polymerase and....” See *id.* The Examiner then considered certain factors set forth in *In re Wands*, 858 F2d 731, (Fed. Cir. (1988)), and made certain allegations about those factors. See *id.* at pages 3 to 7, item 5. In one such allegation, the Examiner contended that applicants’ only working examples are with Pfu DNA polymerase. See *id.* at page 5, item 5.

In the July 2005 Response, applicants asserted that the claims were enabled and, specifically pointed out that the specification included working examples with several different polymerases. See the July 2005 Response at page 3. Applicants then addressed each of the *Wands* Factors addressed by the Examiner and asserted that an analysis of those factors should result in a conclusion that the claims were enabled. See *id.* at pages 3 to 9.

In the Advisory Action, the Examiner maintained the rejection of claims 69, 70, 72, and 74 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. See the Advisory Action, at page 2, item 1. Specifically, the Examiner acknowledged that the specification demonstrates enhancement of nucleic acid polymerase reactions for several different polymerases other than Pfu DNA polymerase. See *id.* The Examiner then alleged that “...it is noted that the specification only demonstrates enhancement of the nucleic acid polymerases selected from the *pyrococcus* species and Vent DNA polymerase but does not teach or demonstrate wherein any other polymerase besides those noted above are capable of being enhanced by the claimed method and PEF composition.” See *id.* The Examiner then specifically addressed the experiments

discussed on page 63 of the specification and alleged that the "...specification clearly shows that the claimed method is not capable of enhancing the activity of any and all nucleic acid polymerases in the art." See *id.* Finally, the Examiner alleged that

"[i]n response to Applicant's arguments that the quantity of experimentation left to one of skill in the art is low, it is noted that contrary to applicant's arguments, one cannot predict the outcome of a nucleic acid polymerase reaction in the presence of an enhancing factor, such as PEF, and any nucleic acid polymerase without further undue experimentation to determine the effects of the enhancing factor on the desired nucleic acid polymerase. Due to the lack of guidance and working examples in the specification, one cannot predict that a desired polymerase reaction will be enhanced using the claimed method as described."

See *id.* at pages 2 to 3. Applicants respectfully traverse.

As applicants noted in the July 2005 Response, "[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 219 (CCPA 1976)." See MPEP §2164.01.

Applicants assert that the experimentation necessary to practice the claimed methods is not undue. Specifically, as noted in *Wands*, "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." See *Wands* at 736-37. A copy of *Wands* is attached.

Here, one skilled in the art could perform routine screening to determine whether a particular polymerase fell within the scope of the claim. The specification provides guidance and working examples (including working examples with several different polymerases) to aid one of skill in the art in enhancing a nucleic acid polymerase reaction with a polymerase enhancing factor. See the specification, e.g., at pages 62 to 65. Furthermore, it was routine in the art at the time the application was filed to perform a nucleic acid polymerase reaction (parent U.S. Patent Application No. 08/822,774 was

filed March 21, 1997). Thus, even if one skilled in the art could not predict the outcome of adding PEF to a particular polymerase reaction comprising a particular polymerase, one could test whether or not PEF enhanced that particular polymerase reaction by simply running two polymerase reactions side by side. The first polymerase reaction would comprise the polymerase but not PEF. The second polymerase reaction would comprise the polymerase and PEF. Comparison of the polymerase reaction products on a gel would reveal whether or not PEF enhanced the polymerase reaction. ***Those experiments could be performed in a matter of hours.***

Furthermore, at the time of filing of the parent priority application, one could perform many different PCR reactions at the same time. For example, by 1997, performing PCR in 96-well plates was common place. See, for example, Udy et al. Biotechniques, 17(5):887-894, 890 (1994), which describes use of 96-well plate PCR as far back as 1994. A copy of Udy is enclosed. Thus, assuming one skilled in the art prepared two PCR reactions for each polymerase, one with PEF and one without PEF, one could test 48 different polymerase and PEF combinations using a single 96-well plate. And one skilled in the art could ***complete the experiment in a matter of hours.*** Applicants assert that those experiments are routine screening and do not constitute undue experimentation.

Thus, applicants assert that the claims are enabled. Accordingly, applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. §112, first paragraph, rejection of claims 69, 70, 72, and 74.

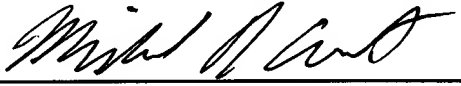
Applicants respectfully submit that the application is in condition for allowance. In the event the Examiner does not find the claims allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6658 to set up an interview.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

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